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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,144	12/15/2003	Su Il Yum	DURE-050	6360
31498	7590	09/11/2007	EXAMINER	
DURECT CORPORATION THOMAS P. MCCrackEN 2 RESULTS WAY CUPERTINO, CA 95014			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/737,144	Applicant(s) YUM ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10-50 and 52-79 is/are pending in the application.
- 4a) Of the above claim(s) 32-40,52-56 and 65-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10-31,41-50,57-64 and 68-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of power of attorney filed 6/15/07; response to election requirement, amendment and remarks, all filed 6/25/07. Claims 3, 9 and 51 are canceled. Claims 1, 2, 4, 5, 10-12, 19-23, 29, 46-50, 52-58, 68, 70 and 78 are amended. Claims 1, 2, 4-8, 10-50 and 52-79 are pending.

Examiner acknowledges this application as claiming benefit of provisional applications 60,433,116 filed 12/13/2002 and 60/517,464 filed 11/4/2003.

Election/Restrictions

1. Applicant's election without traverse of oxycodone as the drug and ethyl lactate as solvent in the reply filed on 6/25/07 is acknowledged. However, claims 52-56 recite organic solvents that are not the elected ethyl lactate, and therefore the claims that do not recite the elected solvent are withdrawn. The claims that read on the elected species are 1, 2, 4-8, 10-31, 41-50, 57-64 and 68-79. Therefore, claims 32-40, 52-56 and 65-67 withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1, 2, 4, 6, 10, 11, 13-31, 41-50, 57-63, 68-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The boundaries of the subject matter of high viscosity liquid carrier material (HVLCM) for which protection is sought are not clear.

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b) The boundaries of the subject matter of network former for which protection is sought are not clear.

c) The boundaries of the subject matter of rheology modifier for which protection is sought are not clear.

Applicant may overcome the above rejection by specifically stating in the claims the meets and bounds of high viscosity liquid carrier material, network former, rheology modifier by reciting the materials applicant deems to have the functional limitation as claimed and as supported by the original disclosure; a Markush language may be used to specifically name those compounds or materials that have the functions applicant seeks protection.

Matters regarding use of Abbreviation:

The claims have used the abbreviations, SAIB, CAB, IPM and EL without initial designation of what those abbreviations are. It is suggested that the terms be initially written out with a parenthetical expression of the abbreviations, which may then be used in the claims without writing the full meaning of the terms.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 57, 70, 71, 76-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Tipton et al. (US 5,747,058).

Tipton discloses a composition comprising HVLCM, and with sucrose acetate isobutyrate specifically employed (abstracts, column 2, lines 43, 46, 55, 60-65; column 4, lines 2-67; column 5, lines 1-33; column 8, lines 51-67; column 12, lines 46-50) meeting the recitation of HVLCM in the claims; the composition contains surfactants (column 11, lines 40-67; column 12, lines 1-17) in amounts of 0.5-30% and having 1-5% preferred that meets network former of the claims and specifically claims 26-29, oily components (column 12, lines 18-45) in amounts of 0.5-50% and with 1-10 preferred meeting the rheology modifier of the claims and specifically claims 23-25, water or DMSO or ethyl lactate or triacetin (column 2, lines 49 and 50; column 12, line 51) meeting the solvent requirements of the claims, additives such as preservative, antioxidants, stabilizers, vitamins (column 12, line 65 to column 13 line 4) meeting claims 17 and 18, and drugs such as codeine (column 7, line 62) meeting claims 29, 30, 70, 71; the formulation of Tipton is placed in gelatin capsules for oral administration (claim 88) meeting claims 13 and 14. Claims 46-50 recite the properties of the composition and the composition of Tipton would inherently possess these properties. The composition of Tipton would inherently possess the characteristics of the composition recited in claims 2 and 4.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al. (US 5,747,058).

Tipton is described above. Tipton describes compositions that contain CAB and HVLCM and solvents separately (see column 4). Regarding the amounts of HVLCM recited in claims 19-22, in the absence of factual evidence, the claimed amounts are not inventive over the prior art. Regarding the amounts of the drugs, it is noted that Tipton teaches percent amounts of drugs and the specific amounts recited in claims 41-45 is not inventive over the percent amounts taught by Tipton in the absence of factual showing of unexpected results. Furthermore, regarding claims 25 and 16, it is noted that the composition of Tipton is encapsulated and use of soft and hard gelatin capsules are known in the art so that it would be obvious to place the formulation in soft or hard gelatin capsule for delivery. Tipton does not disclose one composition that has HVLCM, CAB, solvent, and rheology modifier. But since Tipton teaches these compositions separately, it would be obvious to combine two compositions to form a third composition that would be used for the same purpose. [T]he idea of combining

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them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

9. Claims 31, 63, 64 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al. (US 5,747,058)

Tipton is described above. One of the drugs in Tipton is codeine, which is an opioid. Tipton does not teach the oxycodone in claims 31, 63, 64 and 72. Since oxycodone and codeine are opioids, and specifically, oxycodone is derived from codeine, it is prima facie obvious that oxycodone can be used in place of codeine and expect to obtain similar relative potency.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification including the claims.

Information Disclosure Statement

11. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read 'Blessing Fubara', is written over the printed name of the examiner.